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(54) IMPROVEMENTS IN OR RELATING TO SYRINGES

(71) We, SCHERICO LTD., of Topfertrasse 5, Lucerne, Switzerland, a body corporate constituted under the laws of Switzerland, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to improvements in syringes, in particular syringes for dispensing medicament suspensions.

Syringes for administering medication in the form of a medicament suspension are well known. Such syringes usually comprise a tubular body serving as a container for the medicament suspension, a plunger slidably arranged within the body serving to close one end thereof and operative to dispense the suspension and a nozzle piece through which the suspension may be dispensed. For injection purposes, the nozzle piece may be adapted to receive and engage with a standard hypodermic needle.

Where syringes of the aforementioned type are pre-loaded with a medicament suspension, settling out of the suspended matter during storage can result in solid material being deposited in the passageway of the syringe nozzle piece. This is particularly so for syringes of relatively simple construction such as disposable syringes and where the syringes are stored nozzle down. Such deposited material may frequently form a plug of material in the nozzle piece passage which is not re-dispersed upon shaking the syringe and contents. The plug of material can then be lost in subsequent handling of the syringe by a used, such as upon purging air from the hypodermic needle prior to use for injection purposes. The loss may represent a significant proportion of the suspended active material to be dispensed, particularly where the suspended active material is one of high potency. Overall losses of 10—20% of the total active material may occur.

It is an object of the present invention to provide a syringe which obviates or reduces the aforementioned disadvantage.

According to the present invention there is provided a syringe, assembled or disassembled, comprising a tubular body having a nozzle piece at one end thereof and a plunger insertable into and slidable within the body to close the other end thereof said nozzle piece having a passageway extending longitudinally therethrough to provide a discharge path from the tubular body, wherein said passageway comprises a capillary portion of internal diameter of from 0.3 to 0.7 mm and a distal portion, the distal portion being of internal diameter greater than the capillary portion.

Preferably the internal diameter of the capillary portion of the passageway is 0.4 to 0.6 mm; most preferably the internal diameter is substantially 0.5 mm.

The ratio of the length of the capillary portion of the passageway to the total passageway length may suitably lie between 0.2:1 and 0.8:1.

The internal diameter of the distal portion of the passageway is preferably greater than 1.0 mm and may conveniently be from greater than 1.0 mm to 2.0 mm. The ratio of the length of the distal portion of the passageway to the total passageway length may suitably lie between 0.2:1 and 0.4:1. In a simple and particularly convenient embodiment, the distal portion of the passageway is merely a recess of circular cross-section and of sufficient length to releasably receive a plug or the like member, constituting a closure member, of any suitable construction and with which the passageway walls form a fluid-tight fit. In this embodiment, the syringe may be used in combination with a stopper of conventional design, the stopper having an axially extending protuberance or nipple constituting the closure member.

The overall length of the passageway is not considered critical but may conveniently be from about 7 to 15 mm. Where the syringe is to be used for injection purposes and the nozzle piece is adapted to receive and engage with a standard hypodermic needle, then the dimensions of the mating part of the hypodermic needle will generally dictate the overall length of the nozzle

settled out [redacted]e nozzle piece passageway in the form of a cake or plug which could not be re-dispersed by shaking. From the knowl volume of the passageway and the determined bulk-density of betamethasone dipropionate as 88 mg/ml, the quantity of betamethasone dipropionate in the passageway was calculated as being 0.77 mg or 12% of the total amount of active ingredient. The nozzle piece was then severed and the amount of betamethasone dipropionate determined. The amount was found to be somewhat greater than the calculated quantity.

The aforementioned experiment was also carried out using a syringe in accordance with the invention and employing the same quantity of the betamethasone dipropionate suspension and the same conditions as for the prior art syringe.

In the syringe in accordance with the invention, the axial passageway through the nozzle piece was constituted by a capillary portion of length 7.0 mm and internal diameter 0.5 mm, giving an effective volume for the capillary portion of 1.37 mm^3, and a distal portion of internal diameter 1.15 mm and length 3.0 mm. The stopper, as for the prior art syringe, extended 1.5 mm into the passageway giving an effective volume for the distal portion of the passageway of 1.56 mm^3 and, accordingly, a total passageway volume of 2.9 mm^3. If sedimentation and caking had occurred then based on the determined bulk density of 88 mg/ml, it would have been expected by calculation that 0.26 mg of betamethasone dipropionate would have been deposited.

In fact, severing of the nozzle and determination of the betamethasone dipropionate showed that the passageway of the syringe constructed in accordance with the invention contained only 0.019 mg of betamethasone dipropionate. This corresponds to the amount one would expect in the passageway for a uniform suspension having 6.4 mg/ml of betamethasone dipropionate. Sedimentation and caking of suspended material was thus substantially eliminated.

The syringe in accordance with the invention is particularly applicable for use with suspensions in which the average particle size of the suspended ingredient is less than 50 microns, especially 20 microns or less.

The syringe in accordance with the present invention, as applied to disposable syringes, is considered to be further advantageous in that the capillary portion of the passageway renders it difficult to re-fill the syringe from a vial of a medicament suspension.

While describ[redacted]ith reference to suspensions, it is also apparent that where uniformity of construction is required the syringe of the present invention may be used for dispensing both suspensions and solutions.

WHAT WE CLAIM IS:—

1. A syringe, assembled or disassembled, comprising a tubular body having a nozzle piece at one end thereof and a plunger insertable into and slidable within the body to close the other end thereof said nozzle piece having a passageway extending longitudinally therethrough to provide a discharge path from the tubular body, wherein said passageway comprises a capillary portion of internal diameter of from 0.3 to 0.7 mm and a distal portion of internal diameter greater than the capillary portion.

2. A syringe as claimed in claim 1 further comprises a closure member which may be releasably received by the distal portion of the nozzle piece.

3. A syringe as claimed in claim 2 which includes a stopper member having a protuberance said protuberance constituting said closure member matable in fluid-tight manner with said distal portion of the passageway.

4. A syringe as claimed in any one of claims 1 to 3 wherein the internal diameter of the said capillary portion is 0.4 to 0.6 mm.

5. A syringe as claimed in any one of claims 1 to 4 wherein the ratio of the length of the said capillary portion to the total length of the passageway is between 0.2:1 and 0.8:1.

6. A syringe as claimed in any one of the preceding claims, wherein the said distal portion has an internal diameter of greater than 1.0 mm.

7. A syringe as claimed in any one of the preceding claims, wherein the ratio of the length of the said distal portion to the total length of the passageway is between 0.2:1 and 0.4:1.

8. A syringe as claimed in any one of the preceding claims which further comprises a hypodermic needle.

9. A syringe as claimed in claim 8, wherein the nozzle piece is adapted to slidably receive and engage with a hypodermic needle.

10. A syringe as claimed in any one of the preceding claims in an assembled condition and when charged with a medicament suspension.

11. A syringe as claimed in claim 10,

1550016 COMPLETE SPECIFICATION
1 SHEET

Fig: 1.

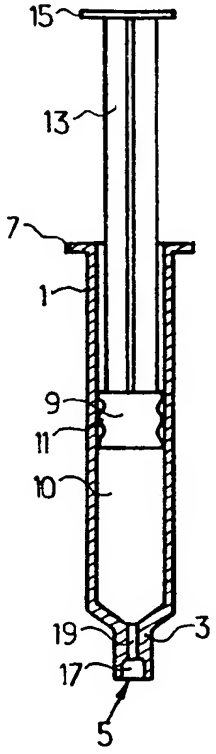

Fig: 2.

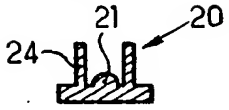

Fig: 3.